N*e*XOS - THE DESIGN, DEVELOPMENT AND EVALUATION OF A REHABILITATION SYSTEM FOR THE LOWER LIMBS

(Running Title – N*e*XOS)

D Bradley[a], C Acosta-Marquez[b], M Hawley[c], S Brownsell[c], P Enderby[d] & S Mawson[e]

[a] (Corresponding Author), CCT, University of Abertay Dundee, Bell Street, Dundee DD1 1HG, UK
Tel ++ 44 (0) 1382 308234, Fax ++ 44 (0) 1382 308627
[b] CETI, Universidad de Bogotá Jorge Tadeo Lozano, Apartado Aéreo 34185, Bogotá D.C., Colombia
[c] ScHARR, University of Sheffield, Sheffield S10 2TN, UK
[d] SISA, University of Sheffield, Sheffield S10 2TN, UK
[e] Centre for Health and Social Care Research, Sheffield Hallam University**,** Collegiate Campus Sheffield S10 2BP, UK

Abstract

Recent years have seen the development of a number of automated and semi-automated systems to support for physiotherapy and rehabilitation. These deploy a range of technologies from highly complex purpose built systems to approaches based around the use of industrial robots operating either individually or in combination for applications ranging from stroke to mobility enhancement. The N*e*XOS project set out to investigate an approach to the rehabilitation of the lower limbs in a way which brought together expertise in engineering design and mechatronics with specilists in rehabilitation and physiotherapy.

The resulting system has resulted in a prototype of a system which is capable in operating in a number of modes from fully independent to providing direct support to a physiotherapist during manipulation of the limb. Designed around a low cost approach for an implementation ultimately capable of use in a patients home using web-baased strategies for communication with their support team, the prototype N*e*XOS system has validated the adoption of an integrated approach to its development. The paper considers this design and development process and provides the results from the initial tests with physiotherapists to establish the operational basis for clinical implementation.

Keywords: Mechatronics, Design, Physiotherapy, Rehabilitation

1. Introduction

The incidence of Spinal Cord Injury (SCI) in the UK is some 10 to 15 cases per million of the population [1], equating to around 600 to 900 new injuries per annum of which 80% are due to trauma and 20% to pathology. There are two age range peaks; 16 to 30 year olds and the 60-plus age group, with the male to

female ratio being 4:1. Zejdlik [2] reported a similar distribution of spinal cord injury for the USA as in the UK.

Maintenance of joint range through passive movements and the teaching of self-stretching for those with a complete loss of function remains a key, and often time-consuming, part of ongoing management of the condition, as well as often being physically demanding on the physiotherapist. For incomplete injuries the rehabilitation and re-education process is likely to begin with passive movements in which the lower limbs are manipulated by the physiotherapist with no input from the patient. As rehabilitation progresses, the therapy will change to active assisted and resisted movements where the patient works with the physiotherapist to develop their muscles as they recover neural control. Functionally-based exercise to maintain or improve independence, as well as prevention of contractures and management of altered tone, is also very important for those with incomplete injuries [3]. All of these various types of movement are associated with and based around the Oxford scale classification for grading muscle strength used by physiotherapists and set out in Table 1.

In addition to the treatment of SCI, the exercising of the lower limbs can also form an important part of the rehabilitation process after certain injuries, subsequent to a stroke or following surgical procedures such as knee joint replacement (Knee Arthroplasty (KA)). The passive movement of the limbs can also act to reduce pain and increase comfort for a range of clinical conditions, as for instance for patients with progressive neurological conditions such as Multiple Sclerosis and Motor Neurone Disease.

While technologies such as the Continuous Passive Motion (CPM) machine [4-6] have been developed to assist physiotherapists in delivering exercise programmes, such systems have not been widely accepted by the profession or indeed by users because of a range of difficulties in use, lack of flexibility, cost and the expertise required to exploit their potential. Further, many attempts to put in place such systems have failed to engage users in the development process, compounding problems of inappropriate design and hence of acceptance.

However, it is increasingly being recognised that automated and robotic systems have the potential to play a role in support of a range of therapies involving the manipulation of the upper and lower limbs as part of the rehabilitation process for a wide range of conditions and the N*e*XOS project funded by the UK

Department of Health through its New and Emerging Applications of Technology (NEAT) programme reflects this developing interest. However, to date much of the emphasis has been on the upper limbs, as for instance the work of Reinkensmeyer *et al* [7], Volpe [8], Eftring [9], Rao [10], Lum [11], the REHABROB project [12] and a commercial system from MuscleTech [13]. Of such systems, perhaps the best known is the MANUS arm [8,14], though the commercial system [15] tends to be used more for living support than therapy and rehabilitation.

For the rehabilitation of the lower limbs, currently available systems include the Hocoma Lokomat system [16], the Leg Extension system from Monitored Rehab Systems [17] and the Therapeutic Exercise Machine (TEM) system from the Yaskawa Electric Co. [18,19]. Of these, the TEM system, developed as an exercise machine to decrease spasticity by repetitively performing a range of motion exercise (ROM-E) for the hip and knee joints of stroke patients, is perhaps the closest to N*e*XOS in terms of its intended function, though it is significantly different in terms of implementation and kinematic configuration.

2. USER REQUIREMENTS

It was clear from looking at previous work in deploying automated systems in support of a range of physical and other therapies that it was essential to engage all potential users as early as possible in the design process. Such early engagement has been shown to have a positive effect on user satisfaction and is an effective means of capturing product and system requirements [20,21]. In the case of the N*e*XOS[‡] project, focus groups with providers and patients were used to establish their views, with data collected using a semi-structured interview schedule. Formal design methods such as viewpoint analysis were then used to capture the technical aspects of system implementation and to link these to the outcomes of the focus groups.

2.1 Provider Requirements

Four focus groups were conducted with physiotherapists drawn from the clinical fields of orthopaedics, spinal cord injuries or community based therapy and were aimed at establishing their perceptions of the potential role(s) for a system for lower limb manipulation and of the requirements for such a system. The

[‡] Derived from **NEAT EXOS**keleton after the project funders, the New and Emerging Applications of Technology (NEAT) programme of the UK Department of Health.

points that emerged were:

2.1.1 Limitations of current equipment

The physiotherapists indicated that there was no really robust evidence to suggest that current CPM systems had a significant impact on patient recovery. There also appeared to be few formal procedures for their use and application tended to be limited to a few complex cases. Current CPM machines are only capable of performing passive movements of the patients lower limb, see Table 1, and have a tendency to pull the patient down the bed, and repeated readjustments are therefore required [22-25].

2.1.2 Usefulness of robotic aid

The availability of a robotic aid was considered particularly relevant for repetitive movements to increase the patients achieved range of movement (ROM) over prolonged courses of therapy as well as for bilateral and specialised conditions such as sports injury and leg lengthening. It was suggested that patients are not discharged until they are considered to have achieved an appropriate range of movement, and that a device such as N*e*XOS could be useful in supporting development such circumstances and would decrease the physical demands on physiotherapists in achieving the desired ROM.

2.1.3 Compliance with and control of therapy

Some physiotherapists suggested that the presence of an aid could make some patients reliant on it, while others suggested that only highly motivated patients would benefit. Physiotherapists also envisaged a requirement to monitor the aid and check all is working appropriately and correctly and indicated a need to feel and touch joints as part of the treatment process. One commented that:

> "*Nothing can substitute that [exoskeleton] for a pair of hands and skill in actually being able to analyse that joint.*"

2.1.4 Location of therapy

It was felt that some patients would benefit from home based therapy based around a robotic aid, but some concerns over legal and safety issues were raised. For example:

"I suppose you've got to be careful, because you don't want to get on it with stiff legs, do you, and have it sort of wrenching around."

However, all of the groups discussed the concept of '*superclinics*' where several systems were physically supervised by a single physiotherapist. This they suggested, was an all win position, as throughput was improved while maintaining the physical contact and interaction with patients.

2.2 Patient Requirements

Four structured focus groups were held with patients with three key themes emerging:

2.2.1 Monitoring function of robotic aid

Participants valued the potential ability of the system to monitor and measure more accurately their progress, as for instance achieved ROM, and improvements in this. They considered that a machine could in some instances perform this more effectively than a physiotherapist.

2.2.2 Motivational factors

Feedback was important to members of the patient groups. They wanted to know if they were improving and identified a robotic aid as having the potential to accurately provide them with this information. They suggested that people stop complying with their programme of therapy when they no longer able to readily perceive, possibly marginal, improvements in their performance, and that a robotic aid could help prevent this.

2.2.3 Contact with physiotherapist

The robotic aid was viewed as part of a package of therapy, and that they as patients would need to have access to a therapist by telephone, over the internet or as a visit from a community physiotherapist. While it was suggested that the therapist can help in providing motivation, the robotic aid was seen as a way of monitoring and measuring progress in the absence of sufficient numbers of physiotherapists and for reducing the number of visits to rehabilitation sessions if home use was possible.

Overall, the focus groups suggested that present systems such as CPM machines were not performing as well as they might and that their limitations meant that there was a reluctance to use them. However, they also identified that a robotic aid had the potential to be useful in a clinical setting, although there remained within the physiotherapist community some resistance to using such a device.

Physiotherapists also suggested that their computer skills were often weak and that this may be a factor in their assessment of the concept of a programmable robotic therapy aid. They also expressed concerns over issues associated with their requirement to 'feel' joints and motions and of their ability to control the therapy. In comparison, patients tended to view the idea of such a system more positively, and believed it could aid in speeding their recovery.

3. SYSTEM DEFINITION

3.1 Definition of Patient Groups

Existing passive motion systems such as CPM machines and the TEM system act only to move the leg through a defined series of movements and require the user to exert no forces during the motion. A key aim of the N*e*XOS approach is to achieve a balance of operation in which motion may range from the purely passive, to active assisted and resistive conditions where the patient would be working against the system, which then provides resistance to motion, for all or part of a cycle. It was envisaged that combinations of passive, active assisted and resisted motion may be provided within a cycle of operation.

This meant that for the purposes of initial evaluation it was necessary to specify prospective user groups whose needs would reflect these requirements in terms of providing and resisting motion. Specifically, there was a need to identify:

- A group whose requirement was for passive movements only but for whom a much greater degree of control over both the type and range of movement than was currently achievable would be beneficial.

- A group whose requirement was for a range of active assisted movements, including the requirement to adjust the response of the system in relation to the achieved ROM.

It was therefore decided to establish the initial investigation around the requirements of individuals undergoing knee arthroplasty (KA) [26,27] and patients with Spinal Cord Injuries (SCI).

3.2 **Functional Analysis**

Having established the basic requirements for the system, it was necessary to perform a functional analysis in order to be able to define the key features associated with meeting the performance. The method chosen for this was viewpoint analysis as this enabled the division of the identified viewpoints into those directly concerned with the physical operation of the exoskeleton (the *functional viewpoints*) and those associated with its integration into clinical and other systems (the *non-functional viewpoints*) [28], resulting in the hierarchies of Figs 1 and 2.

3.3 System Configuration

Using the information obtained from the patient groups and physiotherapists and combining this with the structure provided by the viewpoint analysis, the research was able to consider both the physical structure of the system and its control and the development of user views through a combination of analysis and focus group studies. Specifically, it became possible to establish key requirements for the N*e*XOS system in that it should:

1. Enable a variety of motions and motion types as determined by the physiotherapist in conjunction with the patient.

2. Enable the rapid reconfiguration of the system to encompass different forms of motion based around a range of defined motions.

3. Support the monitoring and control of the forces applied along the axis of the major bones in the lower leg in order to try to alleviate the loss of Bone Mineral Density (BMD).

4. Support a rapid and automatic set-up procedure for any individual patient based on knowledge of that patient's physical dimensions. This would be aimed at enabling patients to set the system up themselves rather than requiring assistance, enabling its use in the home environment.

5. Autonomously adjust, within definable limits, to changes in patient position during the therapy process.

6. Monitor the forces and motions exerted and achieved by the system and the patient throughout a cycle and autonomously adjust these to maintain parameters such as force, velocity and power within agreed and defined limits.

7. Motivate patients through feedback on their performance in relation to agreed norms and by allowing them to assume some degree of control over the rehabilitation process. This would include a dialogue with the system to establish a baseline of relevant activity prior to use, with the work programme then being adjusted accordingly.

8. Provide for '*jerk free*' transitions and operation throughout the cycle.

9. Programming of the system for an individual patient would involve a 'teach and repeat' process in which the physiotherapist would manipulate the lower limb with the patient attached to the system to record the achieved motions for subsequent modification and playback.

By analysing video images of a physiotherapist performing a series of manipulative exercises on the lower limb, information was obtained as to the range and types of movements involved, including information about the velocity profiles over a complete manipulative cycle. This data was then used to construct a mathematical model of the motion of the leg capable of representing patients of different leg lengths as shown in Fig. 3.

3.4 System Hardware Configuration

The configuration of the system is as shown in Fig. 4 and comprises the physical structure, the local controller, the user interface and the physiotherapist's interface. The physiotherapist's terminal is shown as connected to the user system via a network which could be either local, as would be the case in a clinic, or distributed if using the Internet.

A pneumatic system based on linear actuators was selected for the implementation of the system mechanism. While possible problems associated with the provision of an air supply were recognised, this

could be achieved by incorporating a compressor and accumulator as part of the system structure where a local air supply was not available. The advantages of using pneumatic linear actuators, not least in respect of system stiffness, and the ability of a pneumatic system to provide resistance to motion through the modulation of the valves were then considered as outweighing the problems of providing an air supply. The ability of the pneumatic system to use the cylinders as air springs to cushion unexpected motions of the limb was also taken into account, for instance in relation to the onset of any form of spastic event during therapy.

Once the range of motions was established, the options for the implementation of a mechanism based around the use of pneumatic cylinders could be considered. While constraining operation to the sagittal plane of Fig. 5 simplified the mechanism design, there still remained a large number of such options, the configuration finally selected being that shown in Fig. 6 and described by equations 1 to 8.

$$x = X_0 + R.\cos\left(\pi/2 - \theta\right) \tag{1}$$

$$y = Y_0 - R.\sin\left(\pi/2 - \theta\right) \tag{2}$$

when

$$R = L_1 + L_2 \tag{3}$$

where

L_1 is the fixed length of cylinder C_1 and L_2 is its extension

Then

$$L_3 = \sqrt{L_1^{\,2} + L_4^{\,2}} \tag{4}$$

and

$$L_7 = L_5 + L_6 \tag{5}$$

where

L_5 is the fixed length of cylinder C_2 and L_6 is its extension

Now

$$L_8 = \sqrt{(X_0 - X_1)^2 + (Y_0 - Y_1)^2} \tag{6}$$

when

$$L_7{}^2 = L_3{}^2 + L_8{}^2 - 2 \cdot L_3 \cdot L_8 \cdot \cos(\theta + \phi - \alpha) \tag{7}$$

Hence

$$\theta = \cos^{-1}\left(\frac{L_3{}^2 + L_8{}^2 - L_7{}^2}{2.L_3.L_8}\right) - \phi + \alpha \tag{8}$$

Thus, angle θ is determined by the extension of cylinder C_2.

3.5 Interface

Work with focus groups identified the need for both user and physiotherapist interfaces that would support the setup and operation of the system. Specifically, the physiotherapist interface would be required to provide and support access to the information set out in Table 2. On this basis, an initial interface was designed using LabVIEW and used to support the first trials of the system.

Though this interface proved effective in collecting the trials data, it was not considered suitable as a practical interface and a more structured form, incorporating a dialogue with the user as part of the setup process, was produced. Examples of this interface are shown in Figs 7, 8 and 9.

There is one further aspect of the interface that has not as yet been considered in detail within the project, namely that seen by the user while exercising with the system. Various options for providing user feedback on progress have been discussed, but it was felt that a decision could not be reached on the precise nature of this interface until an operational system was available for prospective users to see and experience.

4. IMPLEMENTATION OF N*e*XOS PROTOTYPE

Once the working space for the mechanism had been defined, a model of a leg with three degrees of freedom (3 DoF) was built and used to evaluate the nature and form of the required trajectories. This involved replicating the movements and trajectories performed by the physiotherapists to establish the range of motions required, as expressed by the motion of the point of attachment of the limb to the mechanism. The use of the model leg along with the tracks generated is shown in Figs 10(a) and 10(b) respectively.

Following the selection of the geometrical configuration that best suited the defined workspace, a mock-up of the mechanism was put together and used to adjust and tune the relative positioning of the points of support (X_0,Y_0 and X_1,Y_1 in Fig. 8) for the mechanism. Variations in the selected kinematic configuration such as the connection point between the two actuators were also evaluated to prove the design criteria and to confirm that the pneumatic actuators chosen allowed for different leg sizes to be accommodated. For some leg sizes, a small section of the work space is not reachable using the selected standard length actuators, but the change in trajectory is minimal in these instances and could be overcome by using alternative, non-standard length, actuators.

Referring to Fig. 6 and equations 4 and 5, it is seen that the position of the point of attachment of the mechanism to the ankle may be expressed in terms of the extended length (R) of the upper cylinder and its rotation (θ) from the vertical. The value of θ and the required extension of the lower cylinder for and given value of x and y can then be calculated from the system geometry using the inverse kinematic relationships of equations 9, 10 and 11. The parameters R and θ are measured directly using a precision linear potentiometer and a rotary potentiometer respectively.

$$\tan\left(\frac{\pi}{2}-\theta\right)=\frac{Y_0-y}{x-X_0} \tag{9}$$

when

$$\theta=\frac{\pi}{2}-\tan^{-1}\left(\frac{Y_0-y}{x-X_0}\right) \tag{10}$$

Hence

$$R = \frac{x - X_0}{\cos\left(\frac{\pi}{2} - \theta\right)} \tag{11}$$

Referring back to equations 3 and 8 and Fig. 6, it is seen that R is determined by the extension of cylinder C_1 and θ by the extension of cylinder C_2.

Once the geometry and data collection was confirmed; a structure was designed and manufactured to accommodate both the mechanism and the need for locating it over the bed or plinth. This initial prototype is shown in Fig. 11 and was evaluated by the physiotherapists involved with the project.

The first tests by the physiotherapists revealed that the mechanism was quite difficult to handle and that when manipulating the leg other than along the axis of the pneumatic cylinders, they had to work against the cylinder. No air supply was used with these initial trials that concentrated on establishing the '*feel*' of the system under its self weight and its ease of use during the *programming* phase.

Trials were recorded on video, the analysis of which made it easier to understand the nature of the data being recorded. Physiotherapists with a varied range of experience and background were asked to perform the same movements which were then recorded and analysed in bursts of 25 seconds with a sampling time of 100 ms. Figure 12 then shows the results obtained from two different physiotherapists for nominally, and to a large extent visually, equivalent movements.

After the initial tests, changes to the support structure were implemented to support ease of use. As indicated, physiotherapists had commented adversely about the 'feel' of the first prototype system and a slider was therefore introduced in parallel with the upper cylinder to increase the lateral stiffness and improve guidance. An additional degree of freedom was also added at the point of attachment of the leg to enable the rotation of the foot during manipulation. This improved the feel of the system and allowed the physiotherapist to perform the manipulation on the leg without the impression of having to work against the mechanism that they had experienced with the initial prototype.

Data collected using the revised prototype was then used to generate an averaged or synthetic cycle for each physiotherapist for the specific 'patient'[†]. This synthetic cycle could then be adjusted by the therapist prior to playback, for instance in relation to the repetition rate or the range of motion. The resulting cycle was then played back on a second test rig to evaluate the 'teach and repeat' feature.

Tests were initially carried out to using this rig to define the performance characteristics of the proportional valves and different pressures were evaluated to obtain the required leg movement patterns. The rig was then connected to the model leg used previously as shown in Fig. 13 and the synthesised leg patterns, an example of which is shown in Fig. 16, for the different physiotherapists were replayed and the performance recorded.

Referring to this figure, the rig is playing back the averaged data set as derived from the recorded data for the particular physiotherapist and shows the achieved performance, in the form of the playback data, as recorded by the system sensors. From this it can be seen that the achieved performance is an effective match to the target performance.

5. SAFETY

During the prototype stage of the design emphasis has been placed on the identification of potential safety related issues and their effects on the system as a whole [28,29] with the aim of identifying safety critical issues and highlighting the requirements for their mitigation. Failure Mode Effect and Criticality Analysis (FMECA) worksheets were utilised to formulate a view of the system's safe operating regime and to identify and classify areas of potential risk. This allows for a bottom up approach to be taken which aims to isolate and reduce problems during the design and development stages. The FMECA results produced at this early stage are not fixed and would be continually reassessed as the design progresses.

On the basis of the analysis the following key considerations were identified from among many others:

- User override is considered a requirement for safe operation. This to be achievable using methods matched to individual users and activation would bypass the controller to put system into a defined 'safe' mode.

[†] Patients in this case being members of the research team, no real patients were used with the prototype system.

- Extensive physiotherapist training would be required prior to system use.

The safety studies have also identified a range of component and device specific implementation requirements to ensure the safe operation of the system under all conditions.

6. SUMMARY AND CONCLUSIONS

The N*e*XOS project set out to investigate the design, control and implementation of an aid to the rehabilitation of the lower limbs with the potential to be used within a telehealth environment. As the project evolved, the concept changed from that of an exoskeleton to an external mechanism capable of providing the required motions. This change represented the incorporation of the responses of both physiotherapists and potential users within the design process. Though the resulting system still conformed to the original concept of being capable of being used in a patient's home using the Internet to provide the link between them and their physiotherapist, it emerged that the more likely role in the first instance would be within a clinic environment enabling a single physiotherapist to work with multiple patients, the *superclinic* concept.

The system as expressed in the prototype form described here has demonstrated that it is possible to develop a relatively simple, and low cost, approach to the provision of support for physiotherapy in a range of environments and that the system has the capability of operating autonomously either within a clinic or in the home.

In addition to the original concept, the research to date has revealed a number of other potential applications for the approach, including:

- As a training aid for physiotherapists allowing them to review their achieved motions against a target profile.

- As a recording tool for use with patients undergoing therapy to enable the treatment to be recorded and reviewed as appropriate.

- As a tool to support therapists during the treatment process by removing certain of the physical effort associated with manipulating the limb.

It should also be added that the project proved to be an interesting and significant learning experience for all participants. For the technologists, it required them to develop an understanding of patient and physiotherapist needs, and hence of the requirement to adapt the technology provision to those needs. For the physiotherapists it served to increase their awareness of what technology was able to offer, and of what it could not do, while exposing them to a different perspective and viewpoint of their activities.

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Figures

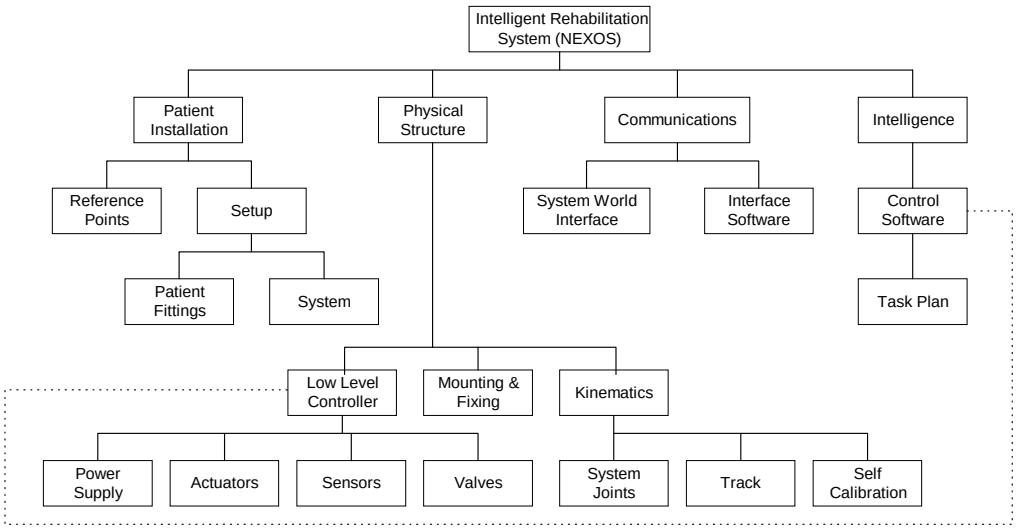


Figure 1: *Functional viewpoints*

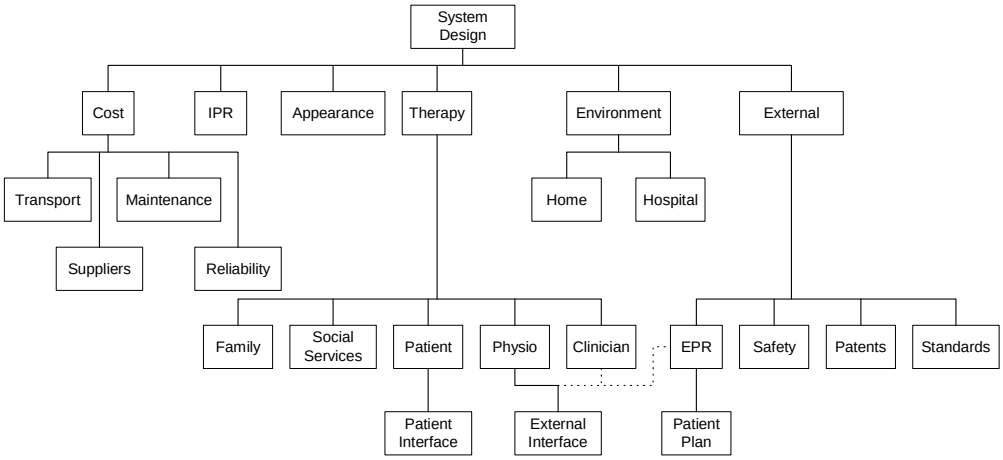


Figure 2: *Non-functional viewpoints*

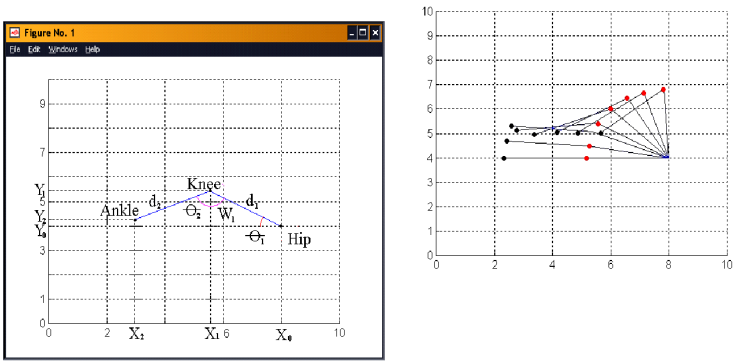


Figure 3: *MatLab model used to assess leg motion for different leg lengths*

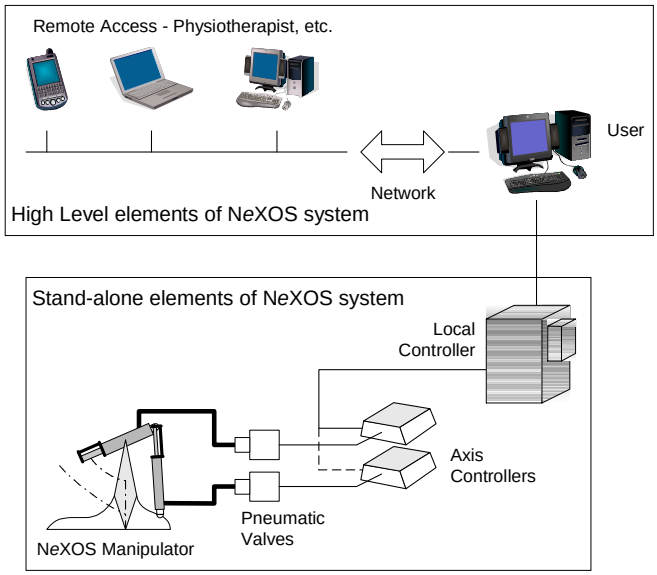


Figure 4: *System configuration*

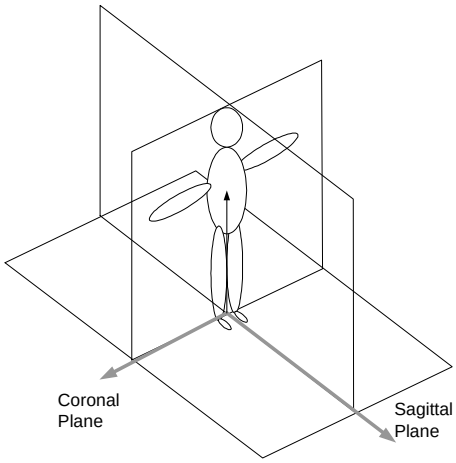
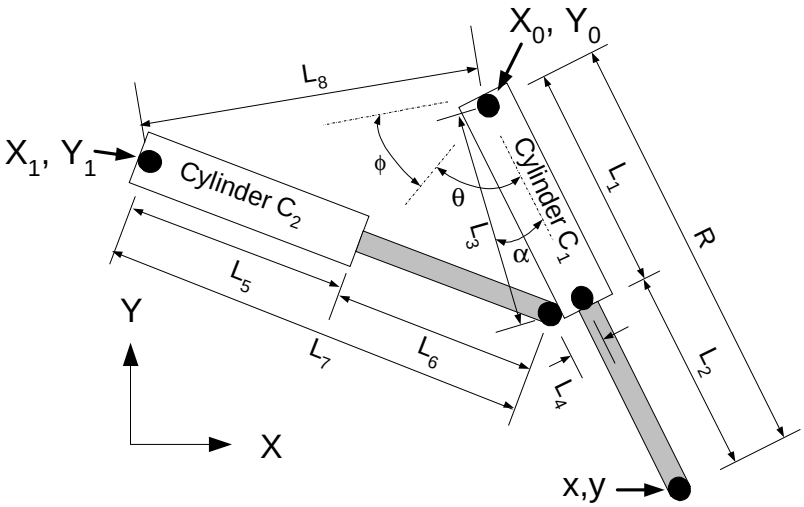


Figure 5: *Sagittal and Coronal Planes*



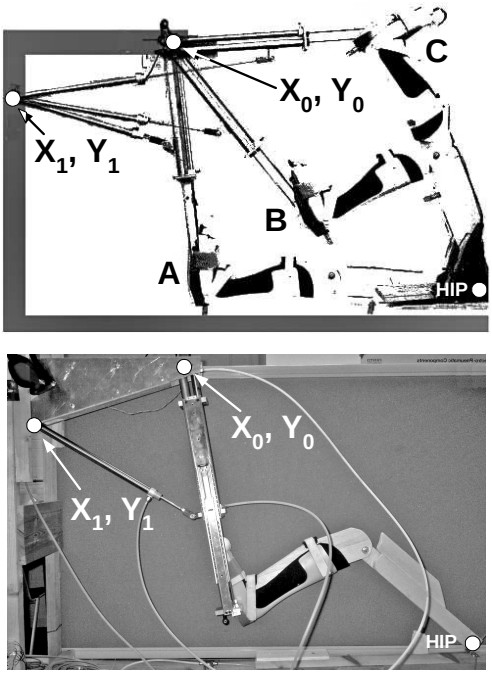


Figure 6: *Selected kinematic configuration*

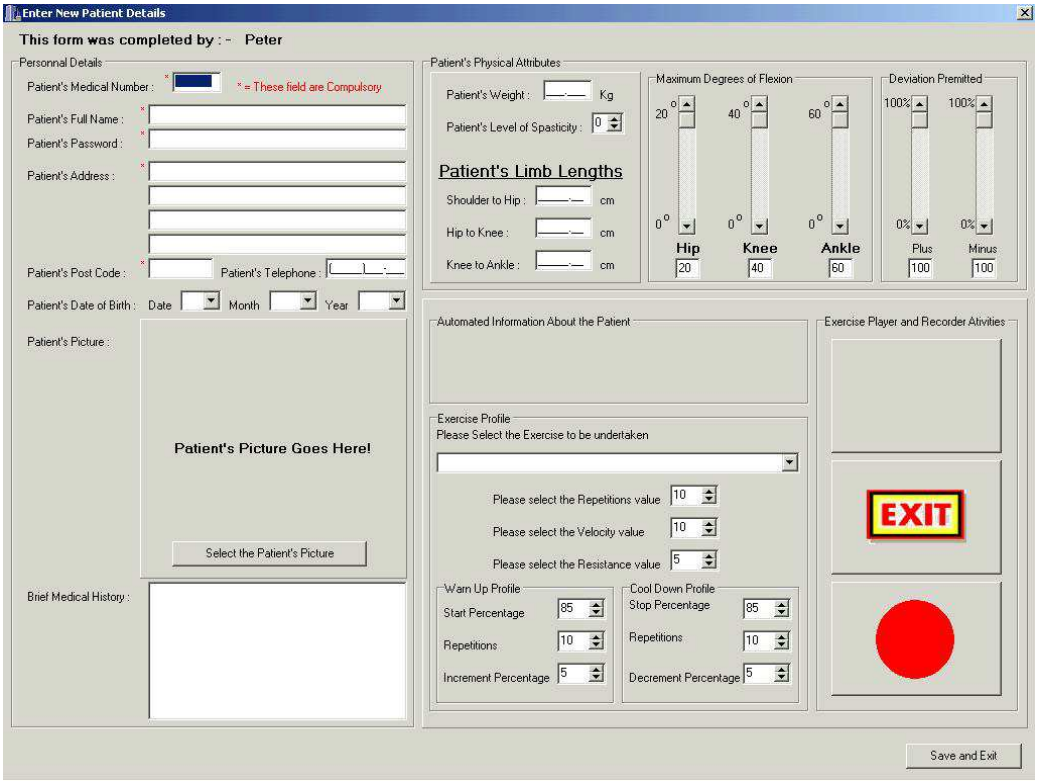


Figure 7: *Patient details*

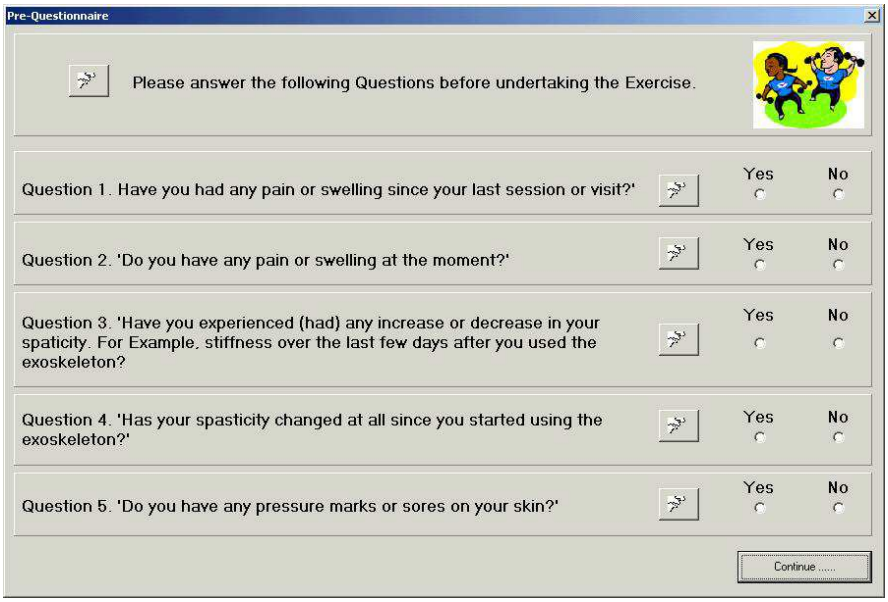


Figure 8: *Pre-exercise dialogue screen*

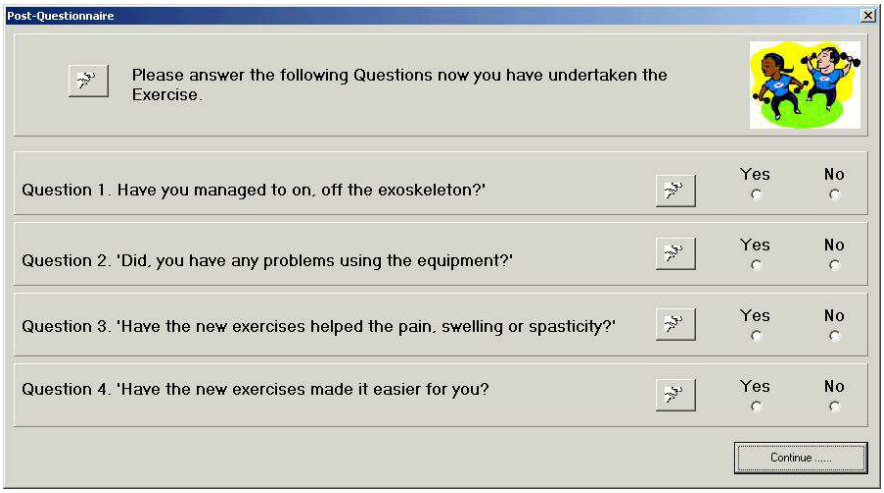
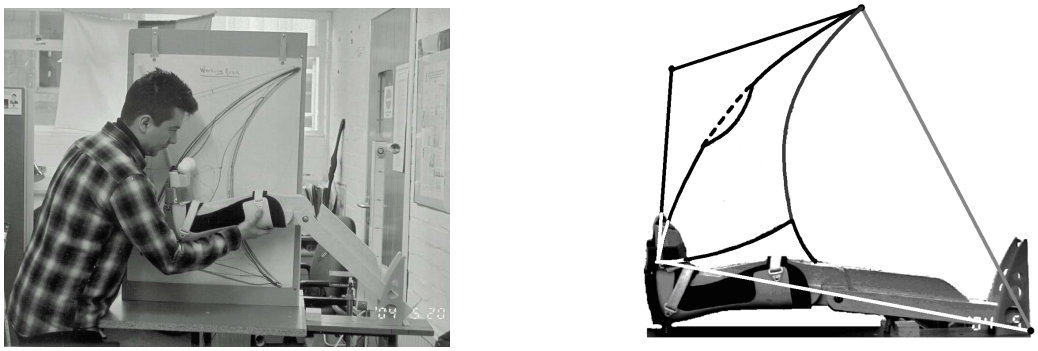


Figure 9: *Post-exercise dialogue screen*



(a) *Leg model in use* (b) *Resulting tracks and envelope*

Figure 10: *Use of model leg to evaluate required motions*

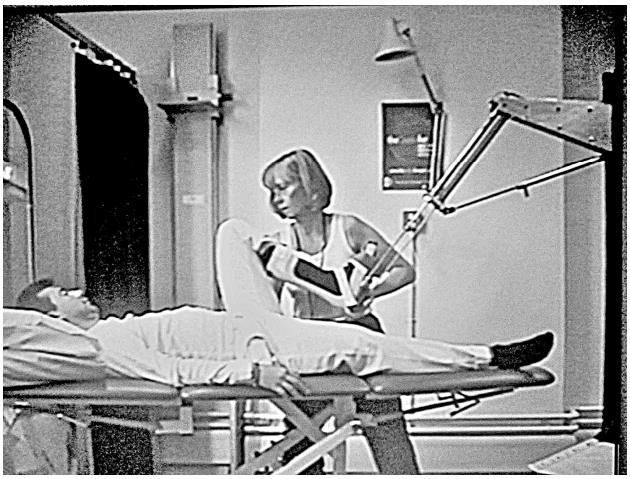
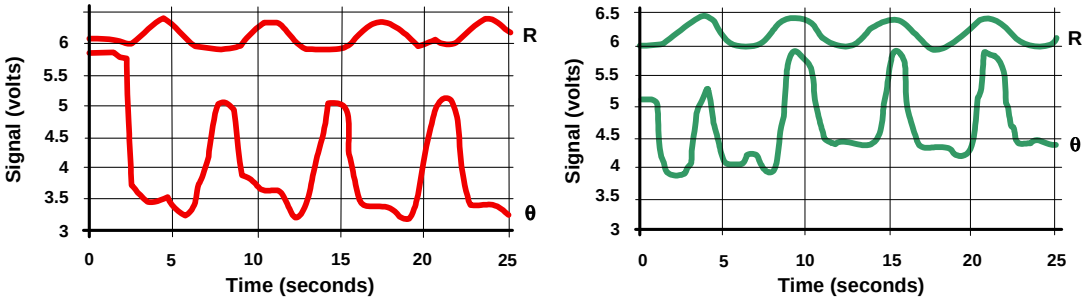


Figure 11: *The first prototype system in use by a physiotherapist to define the required motions*



(a) *Physiotherapist 'A'* (b) *Physiotherapist 'B'*

Figure 12: *Results of trials first prototype system with different physiotherapists*

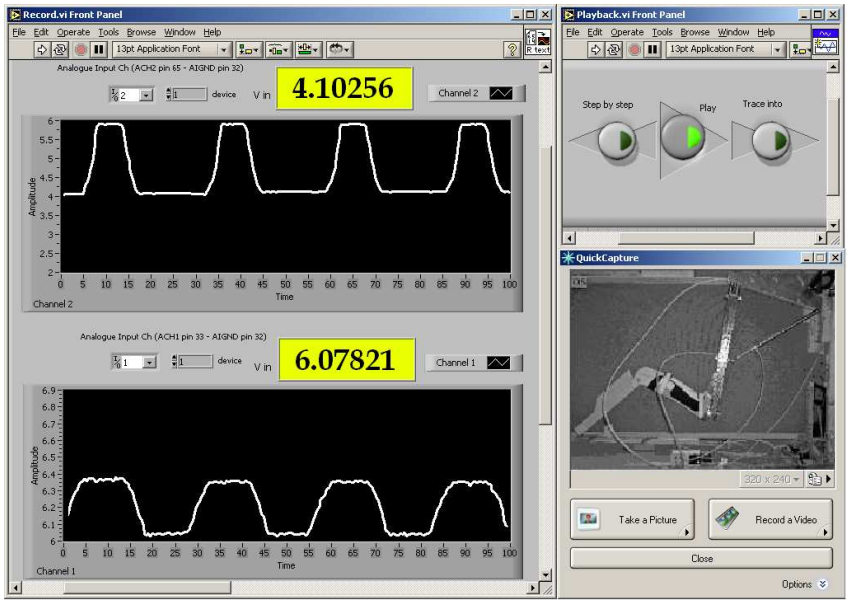


Figure 13: *Test rig with recording and playback software*

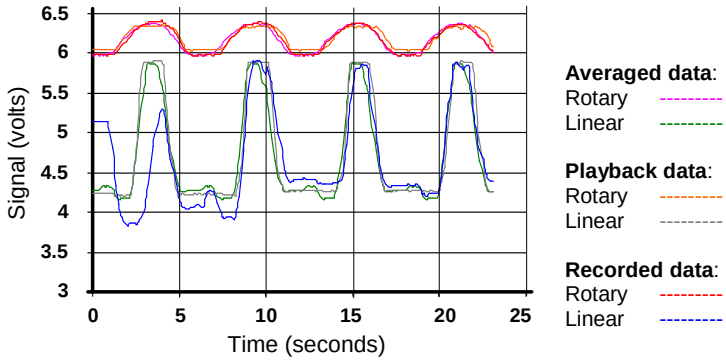


Figure 14: *Comparison of averaged, recorded and playback data.*

Table 1: *Oxford scale for muscle activity*

Grade	Muscle Activity	Motion
0	Nil	Passive
1	A flicker	
2	Weak	Active assisted
3	Moderate with some lift	Resisted
4	Good, can oppose some pressure	
5	Strong opposing pressure / cephalic movement	Functionally active muscle

Table 2: *Physiotherapist interface information requirements*

Patient Identification	Clinical Assessment	Clinical Information	Monitoring
Name	Medical Notes	Dimensions	Performance indicators
Picture	Level of SCI	Movement limitations	Quality of Life rating
ID Number	Management	Movement type	Periodicity
	Associated injuries	Muscle charting	Usage - date & time logs
	History	Spasticity	Reports & comments
		Repetitions	Effort
		Rate	Deviations from baseline
		Exercise type	